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National Dairy Standard - Infant Formulas

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Report Highlights:

On November 20, 2009, China notified the WTO of "National Food Safety Standard of the People's Republic of China for Infant Formulas" as SPS/N/CHN/137. This standard relates to the quality specifications of these milk products. The date for submission of final comments to the WTO is January 1, 2010. The proposed date of entry into force has not been specified.

Executive Summary:

On November 20, 2009, China notified the WTO of "National Food Safety Standard of the People's Republic of China for Infant Formulas" as SPS/N/CHN/137. This standard relates to the quality specifications of these milk products. The date for submission of final comments to the WTO is January 1, 2010. The proposed date of entry into force has not been specified.

According to the WTO notification, "This standard applies to the production, circulation, supervision

and management of infant formulas. It specifies the requirements, testing methods, labeling and packaging for formulas intended for infants."

Thanks go to the consortium of industry and 3rd country Embassies in Beijing for their assistance in translating and reviewing this standard.

This report contains an UNOFFICIAL translation of National Standard on Infant Formulas.

General Information:

BEGIN TRANSLATION

The National Standard of People's Republic of China GB 10765—××× Replacing GB 10765-1997, GB 10766-1997, GB 10767-1997

Infants Formulas

(Draft for approval)

Issued on xx-xx-xxxx

Implemented on xx-xx-xxxx

Issued by the Ministry of Health

of the People's Republic of China

Foreword

This standard is modified in relation to CODEX Standard 72-1981 (Revision 2007) (Part A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants) formulated by Codex Alimentarius Commission and by reference to Chinese *Dietary Reference* Intakes compiled by Chinese Nutrition *Society in* 2000.

This Standard is an integration and amendment to GB 10765-1997, *Infant Formula I*, GB 10766-1997, *Infant Formula II*, *III*, and GB10767-1997, *General Technical Regulations for Infant Blended Milk Powder and Infant Completed Grain Flour*. This Standard replaces GB 10765-1997, GB 10766-1997 and GB 10767-1997.

Compared with GB 10765-1997, GB 10766-1997 and GB 10767-1997, the following changes

have been made to the Standard:
——Integrate the above three standards to one, titled as "Infants Formula";
——Provisions therein are modified.
Annex A of this present National Standard is normative.
The original editions replaced by this present National Standard include:
——GB 10765-1997;
——GB 10766-1997;
——GB 10767-1997.

Infant Formula

1 Scope

This Standard specifies the technical requirements, inspection method, labels, and packaging of infant formulas

This Standard applies to production, circulation, supervision and administration of formulas for infants.

2 Normative References

The following standards contain provisions which, through reference in this text, constitute provisions of this present standard. Note: As for the dated references, all the amendments or revisions after them except the corrigenda are not applicable to this present standard. However, parties to agreements based on this present national standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. As for the references that are not dated, their most recent editions are applicable to this present national standard.

- GB 2760 Hygienic Standards for Uses of Food Additives
- GB 4789.1 Microbiological Examination of Food Hygiene General Principles
- GB 4789.2 Microbiological Examination of Food Hygiene Detection of Total Colony Count
- GB 4789.3 Microbiological Examination of Food Hygiene Detection of Coliform Bacteria
- GB 4789.4 Microbiological Examination of Food Hygiene Examination of Salmonella
- GB 4789.26 Microbiological examination of food hygiene Examination of commercial sterilization of canned food
- GB 4789.40 Microbiological Examination of Food Hygiene Examination of Enterobacter Sakazakii
- GB 5009.1 Methods of food hygienic analysis—Physical and chemical section—General principles
- GB 5009.3 Determination of moisture in Foods

- GB 5009.4 Determination of ash in Foods
- GB 5009.5 Determination of protein in Foods
- GB 5009.12 Determination of Lead in Foods
- GB 5009.24 Method for determination of aflatoxins M_1 and B_1 in foods
- GB 5009.93 Determination of Selenium in Foods
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of lactalbumin
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of Fat
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of Fatty Acid
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of Trans Fatty *Acid*
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of lactose and sucrose
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of Insoluble Dietary Fiber
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of Vitamins A, D, and E content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of vitamin K₁ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of vitamin B₁ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of vitamin B₂ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of vitamin B₆ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of vitamin B₁₂ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of niacin and niacinamide
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of folic acid (folate activity)
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of pantothenic acid
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of vitamin C content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of

- free biotin content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of Choline
- GB xxxx Milk Powder and Formula Foods for Infants and young children--Determination of calcium, iron, zinc, sodium, potassium, magnesium, copper and manganese
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of phosphorus
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of iodine content
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of chlorine
- GB xxxx Milk Powder and Formula Foods for Infants and young children Determination of Inositol
- GB xxxx *Milk powder* and formula foods for infants and young children--Determination of taurine content
- GB xxxx Milk Powder and Formula Foods for Infants and young children *Determination of* Solubility
- GB xxxx Milk Powder and Formula Foods for Infants and young children *Determination of* Impurities
- GB xxxx Milk Powder and Formula Foods for Infants and young children Qualitative Detection of Urease
- GB xxxx Milk Powder and Formula Foods for Infants and young children -- Determination of nitrate and nitrite content
- GB xxxx Milk Powder and Formula Foods for Infants and young children L-Carnitine
- GB 13432 General standard for the Labeling of *Prepackaged* Foods for Special Dietary Uses
- GB 14880 Hygienic Standard for the Use of Nutritional Fortification Substances in *Foods*

3 Terms and Definitions

The following terms and definitions are applicable to this Standard.

- 3.1 Infants: refers to persons of $0 \sim 12$ months old.
- 3.2 Formula for infants: refers to liquid or powder products made only through physical methods, of which the main material is milk and its product, and/ or beans and their products, supplemented with a proper amount of vitamin, minerals and other supplementary materials, which are applicable to normal infants, where the energy and nutrition can satisfy the requirements of growth and development of normal infants of 0~6 months old.

4 Requirements

4.1 Requirements for Raw Materials

- 4.1.1 The raw and supplementary materials should comply with the related national or trade standards or regulations. Non-desalted whey powders should NOT be used. Ingredients and food additives adopted should not contain gluten.
- 4.1.2 Hydrogenated oil and fat should NOT be used.
- 4.1.3 Raw and supplementary materials treated by irradiation should NOT be used.

4.2 Sensory requirement

The color, flavor, smell, structure, and fast dissolvability of the product should meet the requirement on the quality of related products.

4.3 Essential components

- 4.3.1 All ingredients in infant formulas should be fit for feeding of infants, and all essential components should be necessary for growth and development of infants.
- 4.3.2 Necessary ingredients contained per 100kJ (100kcal) infant formula after being mixed or in ready formulas must meet the requirement of Tables 1, 2, and 3.
- 4.3.3 The energy in the ready-to-eat infant formulas per 100ml should be within the range of 250 kJ (60 kcal) ~ 295 kJ (70 kcal). Protein, fat and carbohydrate contained in infant formula should meet the specification in Table 1.
- 4.3.4 When the energy value is identical, the designed content of essential and half-essential amino acid of the infant formula should NOT be less than the amino acid level in breast milk listed in Annex A. *Individual* L type amino acids can be added ONLY for the purpose of improving the protein quality or raising the nutritional value of infant formulas. Sources of the amino acid used should meet the specification of GB14880.
- 4.3.5 For infant formula based on milk protein and its processed products, the preferred carbohydrate should be lactose or the polymer of lactose and glucose. Only after gelation, the starch can be added into the infant formula. Fructose can NOT be used.

Table 1 Index of Protein, Fat and Carbohydrate

Nutrient	Uni t	Per 100 kJ		Per 100 kcal	
		Minimu	Maximu	Minimu	Maximu
		m	m	m	m
Protein ²⁾					
Milk-based					
infant	g	0.45	0.7	1.8	3.0
formula					
Soybean-					
based infant	g	0.5	0.7	2.25	3.0
formula					
Fat 3)	g	1.05	1.4	4.4	6.0

in which: linoleic acid	g	0.07	0.33	0.3	1.4
α- linolenic acid	m g	12	N.S.1	50	N.S. ¹⁾
linoleic acid/α- linolenic acid ratio		5:1	15:1	5:1	15:1
Total carbohydrat e ⁴⁾	g	2.2	3.3	9.0	14.0

¹N.S.: No specification

⁴ The content of lactose in total carbohydrate should be over or equal to 90%.

4.3.6 Vitamin

Indices of vitamin content in the products should meet the specification in Table 2.

Table 2 Indices of Vitamin

Nutrient	Unit	Per 100 kJ		Per 100 kcal	
		Minimu	Maximu	Minimu	Maximu
		m	m	m	m
Vitamin A	μg RE ¹	14	43	60	180
Vitamin D ²)	μg	0.25	0.6	1	2.5
Vitamin E	$\begin{array}{c} mg \\ \alpha\text{-} \\ TE^3 \\) \end{array}$	0.12 ⁴⁾	1.2	0.54)	5
Vitamin K	μg	1	6.5	4	27
Vitamin B ₁	μg	14	72	60	300
Vitamin B ₂	μg	19	119	80	500
Niacin and niacinamide 5)	μg	70	360	300	1500

² For infant formulas based on milk protein and its processed products, the content of lactalbumin should be over or equal to 60%; the content of protein should be calculated as nitrogen (N) \times 6.25; for infant formulas based on beans and their processed products, the content of protein should be calculated as nitrogen (N) \times 5.71.

³ In the finished products, the total content of lauric acid and myristic acid (tetradecanoic acid) should not exceed 20% of the total fatty acid; the maximum content of trans fatty acid should not exceed 3% of the total fatty acid; the erucic *acid content* should not exceed 1% of the total fatty acid.

Vitamin B ₆	μg	8.5	45	35	175
Vitamin B ₁₂	μg	0.025	0.36	0.1	1.5
Pantothen ic acid	μg	96	478	400	2000
Folic acid	μg	2.5	12	10	50
Vitamin C	mg	2.5	17	10	70
Biotin	μg	0.4	2.4	1.5	10

- 1) RE is retinol equivalent. 1 μ g RE=3.33 IU A=1 μ g All trans retinol (Vitamin A). Ingredients of Vitamin A shall come from preformed retinol. When calculating or claiming activities of Vitamin A, no carotenoids ingredient shall be included.
- 2) Calciferol, 1µg Calciferol = 40 IU Vitamin D
- 3) 1 mg α -TE (α -tocopherol equivalent)=1 mg d- α -tocopherol.
- 4) The content of Vitamin E should be at least 0.5mg of α -TE per gram of polyunsaturated fatty acid. The minimum of Vitamin E content should be regulated according to the number of double bonds in polyunsaturated fatty acids in the formula as follows: 0.5 mg of α -TE per gram of linoleic acid (18:2 n-6); 0.75 mg of α -TE per gram of α -linolenic acid (18:3 n-3); 1.0 mg of α -TE per gram of arachidonic acid (20:4 n-6); 1.25mg of α -TE per gram of Eicosapentaenoic Acid (20:5 n-3); 1.5mg of α -TE per gram of docosahexenoic acid (22:6 n-3).
- 5) Niacin: excludes precursor form.
- 6) Expressed by ascorbic acid.

4.3.7 Minerals and microelements

The indices of minerals in infant formulas should meet the specification of Table 3.

Table 3 Indices of Minerals

Nutrient	Uni t	Per 100 kJ		Per 100 kcal	
		Minim	Maxim	Minim	Maxim
		um	um	um	um
Sodium	mg	5	14	20	60
Potassium	mg	14	43	60	180
Chloride	mg	12	38	50	160
Calcium	mg	12	35	50	140
Phosphorus	mg	6	24 1)	25	100 1)
Calcium/phosph orus ratio		1:1	2:1	1:1	2:1
Magnesium	mg	1.2	3.6	5	15 ¹)
Iron	mg	0.1	0.36	0.45	1.5
Zinc	mg	0.12	0.36	0.5	1.5
Manganese	μg	1.2	24	4.8	100
Iodine	μg	2.5	14	10	60

Selenium	μg	0.48	1.9	2	8
Copper	μg	8.5	29	35	120
1) Only applicable to fe	ormula	s based on milk	protein and its h	ydrolyzed prod	ucts.

4.4 Optional components

4.4.1 In addition to the essential components in 4.3, other components found in human milk, or those that have been verified to have similar feeding effect to similar components in human milk, can also be added, whereas the scope of applicability and category should meet the related regulations of the state. One or more nutrients listed in Table 4 can be selected, whereas the content of such nutrients should meet the specification of Table 4.

Table 4 Indices of Optional Components

Optional Components	Unit	Per 100 kJ		Per 100 kcal	
-		Minimum	Maximum	Minimum	Maximum
Taurine	mg	NS	3	NS	12
Choline	mg	1.7	12	7.0	50
Inositol	mg	1.0	9.5	4.0	40
L-Carnitine	mg	0.3		1.2	
Docosahexaenoic	%	NS	0.5	NS	0.5
acid	total				
	fatty				
	acid				
Arachidonic	%	NS	1	NS	1
acid	total				
	fatty				
	acid				

¹⁾ If docosahexaenoic acid (22:6 n-3) is supplemented to the infant formula, at least the same amount of Arachidonic acid (20:4 n-6) should be supplemented. Eicosapentaenoic acid (20:5 n-3) may exist in long chain unsaturated fatty acids, of which the total content should not exceed that of docosahexaenoic acid.

- 2) NS: No specification.
- 3) During calculation of total fatty acid, C4 ~ C24 fatty acid should be involved.
 - 4.4.2 Other nutrients not shown in Table 4 can also be added to infant formulas, whereas such nutrients should comply with related regulations.

4.5 Other indices

Other indices of the components in infant formulas should meet the specification of Table 5.

Table 5 .Other Indices

Item		Index
Water content, % ^①	<u></u>	5.0

Ash, [©]		
Milk based products, % ≤		3.5
Bean based products, milk and bean based products, %	<u> </u>	5.0
Impurities (for milk based product ONLY)		
Powder product, mg/kg ≤		12
Liquid product, mg/kg ≤		2
① Only for powder products.		

4.6 Nutrient compounds

Nutrient compounds that can be used in infant formulas should comply with GB14880.

4.7 Food Additives

Food additives that can be used in infant formulas should comply with GB 2760.

4.8 Hygienic requirements

4.8.1 Indices of contaminants

Indices of contaminants in the products should meet the specification of Table 6. It is not allowed to add fluorin to infant formula.

Table 6 Indices of Contaminants (calculated based on dry matter)

Item	Index
Lead, mg/kg ≤	0.15
Nitrate (based on NaNO ₃), mg/kg ≤	100
Nitrite (based on NaNO₂) ^① , mg/kg ≤	2
Aflatoxin M_1 or Aflatoxin B_1^{\circledcirc} , $\mu g/kg$ \leq	0.5

① Determination of nitrite is not necessary for bean-based products.

4.8.2 Indices of Microorganisms

Indices of Microorganism in infant formulas should meet the specification of Table 7; the liquid infant formulas should meet the requirement of commercial sterilization.

Table 7 Indices of Microorganisms

Microorganism	Sampling plan ^a and limit (Unless specified otherwise, it should
Wilefoorgamsiii	be expressed in cfu/g)

② The index of Aflatoxin M_1 is applicable to products of which the main materials are cow's (or other animals') milk and its products; the index of Aflatoxin B_1 is applicable to products of which the main materials are beans and their products; the indices of Aflatoxin M_1 and Aflatoxin B_1 are applicable to products of which the main materials are cow's (or other animals') milk and its products, and beans and their products.

	n	С	M	M
Total colony count b	5	2	1000	10000
Coliform bacteria	5	2	10	100
Enterobacter sakazakii ^c	3	0	0/100 g	-
Salmonella	5	0	0/25 g	-

a. Comply with 4.2.1 of GB/T 4789.1

- b. Not applicable to products supplemented with probiotic bacteria.
- c. Only applicable to formulas for infants of 0-6 months old. NOT applicable to formulas for infants of 6-12 months old

4.8.3 Urease

The activity of urease is ONLY for bean-based product. The result of qualitative detection should be negative and the quantitative detection should be less than 0.02 U/g.

5 Inspection method

5.1 Energy density

The determined values of protein and fat and the calculated value of carbohydrate multiply the energy factor, 17 kJ/g, 37 kJ/g, and 17 kJ/g respectively, and the sum is the value in kilo Joule per 100 g (kJ/100g); or the determined values of protein and fat and the calculated value of carbohydrate multiply the energy factor, 4 kcal/g, 9 kcal/g, and 4 kcal/g respectively, and the sum is the value in kilo calorie per 100 g (kcal/100g).

5.2 Protein

Determine according to the method specified in GB 5009.5.

5.3 Lactalbumin

Determine according to the method specified in GB xxxx

5.4 Fat

Determine according to the method specified in GB xxxx.

5.5 Linoleic acid, lauric acid, myristic acid, erucic acid, DHA (Docosahexaenoic acid), and Arachidonic acid.

Determine according to the method specified in GB xxxx.

5.6 Trans fatty acid

Determine according to the method specified in GB xxxx.

5.7 Calculation of carbohydrates

The mass fraction A1 of carbohydrate is calculated as per formula (1):

$$A_1 = 100 - (A_2 + A_3 + A_4 + A_5 + A_6)$$
 (1)

Where.

 A_I —Mass fraction of carbohydrate, %;

 A_2 —Mass fraction of Protein, %;

 A_3 —Mass fraction of Fat, %;

 A_4 —Mass fraction of Moisture, %;

 A_5 —Mass fraction of Ash, %;

 A_6 —Mass fraction of insoluble dietary fiber, %.

5.8 Sucrose

Determine according to the method specified in GB xxxx.

5.9 Insoluble dietary fiber

Determine according to the method specified in GB xxxx.

5.10 Vitamins A, D, E

Determine according to the method specified in GB xxxx.

5.11 Vitamin K

Determine according to the method specified in GB xxxx.

5.12 Vitamin B₁

Determine according to the method specified in GB xxxx.

5.13 Vitamin B₂

Determine according to the method specified in GB xxxx.

5.14 Vitamin B₆

Determine according to the method specified in GB xxxx.

5.15 Vitamin B_{12}

Determine according to the method specified in GB xxxx.

5.16 Niacin and niacinamide

Determine according to the method specified in GB xxxx.

5.17 Folic acid

Determine according to the method specified in GB xxxx.

5.18 Pantothenic acid

Determine according to the method specified in GB xxxx.

5.19 Vitamin C

Determine according to the method specified in GB xxxx.

5.20 Biotin

Determine according to the method specified in GB xxxx.

5.21 Choline

Determine according to the method specified in GB xxxx.

5.22 Calcium, iron, zinc, sodium, potassium, magnesium, copper and manganese Determine according to the method specified in GB xxxx.

5.23 Phosphorus

Determine according to the method specified in GB xxxx.

5.24 Iodine

Determine according to the method specified in GB xxxx.

5.25 Chlorine

Determine according to the method specified in GB xxxx.

5.26 Inositol

Determine according to the method specified in GB xxxx.

5.27 Taurine

Determine according to the method specified in GB xxxx.

5.28 Solubility

Determine according to the method specified in GB xxxx.

5.29 Impurity

Determine according to the method specified in GB xxxx.

5.30 Ash

Determine according to the method specified in GB xxxx.

5.31 Water

Determine according to the method specified in GB xxxx.

5.32 Urease activity

Determine according to the method specified in GB xxxx.

5.33 Nitrate and nitrite

Determine according to the method specified in GB xxxx.

5.34 Selenium

Determine according to the method specified in GB xxxx.

5.35 Lead

Determine according to the method specified in GB 5009.12.

5.36 Aflatoxins M₁ and B₁

Determine according to the method specified in GB 5009.24.

5.37 L-Carnitine

Determine according to the method specified in GB 17787.

5.38 Commercial sterilization

Determine according to the method specified in GB 4789.26.

5.39 Colony count

Determine according to the method specified in GB 4789.2.

5.40 Coliform Bacteria

Determine according to the method specified in GB 4789.3.

5.41 Enterobacter sakazakii

Determine according to the method specified in GB 4789.40.

5.42 Salmonella

Determine according to the method specified in GB 4789.4.

6 Labeling, packaging, transportation and storage

6.1 Labels

- 6.1.1 Contents indicated on the label should be subject to specifications of GB 13432. In addition, nutrient ingredients should be indicated as "content per 100 kJ or 100 kcal".
- 6.1.2 On the label, product type and applicable infant age should be indicated. Label of the formula applicable to infants over 6 months old should be indicated with "If this product serves infants elder than 6 month, supplementary foods should also be used".
- 6.1.3 Label of the infant formula should be indicated with "the most ideal food for infants is breast milk; when breast milk is absent or not enough, this product can be used."
- 6.1.4 Images of infants or women cannot appear on the labels. It is not allowed to use the expressions such as "like human milk", "like breast milk" or similar terms.

6.1.5 Directions for use

- 6.1.5.1 The directions for use, proper preparation and illustration as well as storage condition of the product should be clearly indicated on the label. If maximum surface area of the package is less than 100 cm² or if the quality of product is less than 100 g, illustration is not necessary.
- 6.1.5.2 The directions indicated should cover warning on the hazard to health resulting from incorrect preparation or application.

6.2 Packaging

- 6.2.1 Containers and packaging materials of the products should meet the requirement of the related national standards.
- 6.2.2 Packages should be completely sealed; Carbon dioxide and/or nitrogen may serve as packaging medium.
- 6.2.3 Under normal conditions, packages used should not break or be contaminated.

Annex A

(Normative index)

Essential and Semi-essential Amino Acids in Human Milk

By reference to the representative data that have been published related to nitrogen content and/or protein content in human milk in China, the content of essential and semi-essential amino acids in human milk can be calculated, and expressed in milligram per gram of nitrogen and per 100 kcal.

In Attached Table 1 to this national standard, the amino acid content in 100 kcal of infant formula, of which the lower limit level of protein is 1.8g/100kcal, can be calculated according to the mean content of each amino acid in human milk (mg/g nitrogen): The amino acid level (in milligram) per gram of nitrogen in human milk is divided by the nitrogen conversion factor, 6.25, and then multiplied by 1.8.

For all data studied, the mean content and mean value of each amino acid is converted to the average content of each amino acid per gram of protein and per 100 kcal of energy (total nitrogen content $\times 6.25$), as shown in the table below.

Attached Table 1: Mean Content of Amino Acid in Human Milk of China (mg)

Amino acid	mg/gN	mg/100kcal
Cystine	94.2	27.1
Histidine	156.5	45.1
Isoleucine	362.0	104.3
Leucine	643.6	185.4
Lysine	411.4	118.5
Methionine	77.8	22.4
Phenylalanine	223.1	64.3

Threonine	296.4	85.3	
Tryptophan	122.2	35.2	
Tyrosine	226.6	65.3	
Valine	361.8	104.2	